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FOCUS Radiation Treatment Planning System Special 510(k)
Intensity Modulated Radiation Therapy (IMRT)
510(k) Summary of Safety and Effectiveness

Submitter Name:	Computerized Medical Systems, Inc.
Submitter Address:	1145 Corporate Lake Drive St. Louis, MO 63132-1716
Submitter Phone:	314 993 0003
Submitter Fax:	314 993-0075
Contact Person:	Michael A. Parsons - Director - Quality Assurance and Regulatory Affairs
Date Summary Prepared:	June, 2000
Device Trade Name:	FOCUS Radiation Treatment Planning System
Device Common Name:	Radiation Treatment Planning System
Device Classification:	System, Simulator, Radiation Therapy per 21CFR892.5840
Substantial Equivalence:	ADAC Pinnacle^3 Radiation Treatment Planning System - K993923 & K951581 NOMOS Peacock System - K963258 Picker International Acqsim Simulator/Localizer - K923851 Helax TMS - K993766

Device Description: The FOCUS Radiation Treatment Planning System accepts a) patient diagnostic imaging data from CT scans or from films and b) "source" dosimetry data, typically from a linear accelerator. The system then permits the user to display and define (contour) a) the target volume to be treated and b) critical structures which must not receive above a certain level of radiation, on these diagnostic images. Based on the

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prescribed dose, the user, typically a Dosimetrist or Medical Physicist, can then create multiple treatment scenarios involving the number, position(s) and energy of radiation beams and the use of treatment aids between the source of radiation and the patient (wedges, blocks, ports, etc.). The FOCUS system then produces a display of radiation dose distribution within the patient, indicating not only doses to the target volume but to surrounding tissue and structures. The "best" plan satisfying the prescription is then selected, one which maximizes dose to the target volume while minimizing dose to surrounding healthy volume. The parameters of the plan are output in hard-copy format for later reference and for placement in the patient file.

The software modules to permit Intensity Modulated Radiation Therapy (IMRT) planning via Inverse Planning (IP) were developed by CMS based on research performed by the Department of Radiation Oncology of Stanford University located in Stanford, California and provided, under contract, to CMS. This addition to the system in no way changes FOCUS' original intended use.

IMRT capability is being added for users wishing to treat using this new method. No claims are made relative to improved tumor coverage, dose escalation or local tumor control.

The goal of the Inverse Planning feature which was added earlier was to reduce the time-consuming task of determining a treatment set-up for a patient. (No claims are made relative to the plans being 'better' than achievable without the features. Nor are claims made relative to being able to increase tumor dose and thereby provide 'better therapy' because of the use of the feature.) The first use of this Inverse Planning feature was to permit more timely creation of conventional (i.e., non-IMRT) therapy plans. However, because of the complexity of an IMRT plan, all IMRT plans must be created using Inverse Planning.

In **IMRT** planning, tumor dose definition, patient contouring and constraint identification proceeds as with conventional planning. After this point, significant differences between conventional and IMRT planning are seen. For instance, rather than just one, there are multiple set-ups for a given beam position, typically on the order of 5 to15. And, for each set-up, the only treatment aid is the Multileaf Collimator (MLC); there are no blocks ports or wedges. It is the repositioning of the leaves which both produces a unique dose pattern and yields a beam intensity that is "modulated". The IMRT software module optimizes beam positions and MLC sequences to meet the prescribed dose, target volume and constraints input at the start of planning. All dose calculation is performed using the existing, validated dose calculation algorithms within FOCUS.

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Given the time currently required to create a plan where there was just one set-up per beam position, the creation of IMRT plans had previously been impractical in the clinical setting. However, the introduction of Inverse Planning changed all this.

After the tumor dose has been prescribed and the contouring of the tumor volume and critical structures is complete, the user can select Conventional or **Inverse Planning**. When doing Conventional Planning, the Dosimetrist begins manually attempting various combinations of beam placement and weight along with treatment aids to arrive at a treatment plan which satisfies the prescription. For complex cases, or cases where a treatment plan of the type required has not been performed previously, it may take in the range of 2-4 hours to arrive at an acceptable set-up. After the plan is generated and reviewed by the Dosimetrist, it is also reviewed by the Medical Physicist and then by the prescribing Radiation Oncologist prior to starting therapy.

Using Inverse Planning, contouring proceeds as with standard planning. After that, the Dosimetrist identifies whatever constraints are to be placed on the plan (prescribed tumor dose, critical structure dose, number of beams, types of treatment aids available, etc.) and whether Conventional or IMRT therapy is to be used. If conventional inverse planning is chosen, FOCUS automatically creates a plan which satisfies these constraints. The plan is run through the FOCUS dose calculation algorithm and the final plan, including isodose presentations, is reviewed as before. If IMRT therapy is selected, FOCUS invokes the previously-mentioned IMRT module and a plan is created.

Device Intended Use: The FOCUS RTP System with will continue to be used to create treatment plans for any cancer patient for whom external beam radiation therapy or brachytherapy has been prescribed.

The system will calculate and display, both on-screen and in hard-copy, either two- or three-dimensional radiation dose distributions within a patient for a given treatment plan set-up.

Summary of Technological Characteristics Compared to Predicate Devices: The IMRT capability described in this 510(k) will be modules "added-on" to the existing FOCUS Radiation Treatment Planning System previously cleared under K915691 in February, 1995 and K973936 in June, 1998. The FOCUS System with IMRT planning capability incorporates no technological characteristics not currently in the predicate RTP devices.

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The FOCUS System supports most Linear Accelerators, has 3-D visualization capabilities and can perform both 2-D and 3-D treatment planning. Beam's Eye View (BEV) presentation is available as is a Time/MU calculator. The predicate system uses a Pencil Beam algorithm to perform dose calculations both in determining the treatment plan set-up and for final dose calculation whereas FOCUS uses the dose calculation algorithms previously validated on FOCUS. The predicate system uses a UNIX-based workstation for the user interface and graphics presentations and a PC-based dose calculation engine while FOCUS runs entirely on a UNIX-based workstation. The predicate device was validated for use only with its own MLC (MIMIC) whereas this FOCUS release is designed to work with the both Varian and Siemens linacs.

Summary of Clinical Testing: Actual testing in a clinic was not performed as part of the development of this feature. Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness of the device. Clinically-oriented validation test cases were written and executed to assure the device satisfies customer expectations. The actual process of dose calculation and display remains unchanged.

Summary of Non-Clinical Testing: The results of testing on the IMRT feature can be found in the *IMRT Algorithm Test Report* which is included in Tab 14 of this Special 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2000

Michael A. Parsons
Director, Quality Assurance & Regulatory Affairs
Computerized Medical Systems, Inc.
1195 Corporate Lake Drive
St. Louis, MO 63132

Re: K002147
FOCUS Radiation Treatment
Planning System
Dated: July 14, 2000
Received: July 17, 2000
Regulatory Class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Mr. Parsons:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Statement of Indication for Use

510(k) Number: K002147

Device Name: FOCUS Radiation Treatment Planning System with Intensity Modulated Radiation Therapy Planning Capability

Purpose: To calculate and display, both on-screen and in hard-copy, either two- or three-dimensional patient radiation dose distributions based on user-defined treatment plan parameters.

Function: The FOCUS Radiation Treatment Planning System accepts a) patient diagnostic imaging data from CT scans or from films and b) "source" dosimetry data for a linear accelerator. The user then defines (contours) both a target volume to be treated and critical structures where radiation exposure must be kept below some value. They then proceed manually creating a treatment plan. Optionally, the user may select the Inverse Planning capability which has the FOCUS System automatically create multiple possible treatment plans based on some user-defined constraints and the prescribed dose to the tumor volume. The addition of IMRT capability permits the planning for delivery of spatially non-uniform radiation doses.

Concurrence of the Center for Devices and Radiological Health,
Office of Device Evaluation (ODE)

Prescription Use ✓ OR per 21 CFR 801.109 Over the Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002147